

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA

v.

Criminal Action No. 15-CR-10076-ADB

WILLIAM FACTEAU,
PATRICK FABIAN

Defendants

**ORDER ON THE DEFENDANTS'
PRELIMINARY MOTION TO COMPEL DISCOVERY**

October 28, 2015

CABELL, U.S.M.J.

The Government charges Defendants William Facteau and Patrick Fabian in an 18 count indictment with fraudulently inflating the value of their former employer, Acclarant, by knowingly promoting the off-label use of one of Acclarant's products, the Stratus. (Dkt. No. 1). Currently before the Court is the Defendants' Preliminary Motion to Compel Discovery (Dkt. No. 83), which seeks an order compelling the production of seven different categories of information.

I. ANALYSIS

The Defendants contend the Government is obligated to produce the information sought through this Motion under *Brady v. Maryland*, 373 U.S. 83 (1963), and/or Federal Rule of Criminal Procedure 16.

Under *Brady* and its progeny, “the Government must produce exculpatory evidence which is material to guilt or punishment.” *United States v. Pesaturo*, 519 F. Supp. 2d 177, 191 (D. Mass. 2007) (citing *Brady*, 373 U.S. at 87). At the pretrial discovery stage, evidence is material under *Brady* if it “may be favorable to the accused.” *Id.* at 189 n. 7 (citing *United States v. Safavian*, 233 F.R.D. 12, 16 (D.D.C. 2005)). *Brady* does not authorize fishing expeditions into the Government’s files; the burden is on Defendants to make a *prima facie* showing of materiality. *United States v. Bulger*, 928 F. Supp. 2d 305, 324 (D. Mass. 2013).

Rule 16 requires the production, upon request, of those documents “material to preparing the defense.” Fed. R. Crim. P. 16(a)(1)(E). Rule 16 is not limited to evidence that is helpful to a defendant’s case because “[i]t is just as important to the preparation of a defense to know its potential pitfalls as to know its strengths.” *Safavian*, 233 F.R.D. at 15 (citations omitted). Again, the burden is on the Defendants, who must demonstrate that the requested evidence has “more than some ‘abstract logical relationship to the issues in the case.’” *United States v. Poulin*, 592 F. Supp. 2d 137, 143 (D. Me. 2008) (citations omitted).

The Government’s obligation under both *Brady* and Rule 16 is limited to documents in the Government’s possession, custody, or control. The Government must disclose information maintained by agencies “acting closely with the prosecution.” *Safavian*, 233 F.R.D. at 16. It is not obligated to produce information “in the possession of agencies not involved in the investigation.” *Ruiz v. United States*, 221 F. Supp. 2d 66, 74 (D. Mass. 2002) (citations omitted); see also *United States v. Hall*, 434 F.3d 42, 55 (1st Cir. 2006).

With these principles in mind, the Court addresses each of the Defendants’ requests for production.

A. Communications Regarding Prior Johnson & Johnson (“J&J”) Settlement

The Defendants seek documents regarding the FDA’s investigation of and 2013 settlement with J&J stemming from unrelated conduct that occurred prior to J&J’s acquisition of Acclarant. The Defendants argue that this information is material and exculpatory because it tends to show that J&J stopped promoting the Stratus because its settlement obligations made it overly-cautious, and not because J&J believed it was actually unlawful to promote the Stratus. The Government responds that the Defendant’s materiality argument is too speculative and that, even assuming the information is material, the government does not have any responsive documents in its possession, custody or control.

The Court agrees that to the extent the Defendants seek materials involving ostensibly unrelated investigations or matters between J&J (or related entities) and DOJ/governmental entities aside from the U.S. Attorney’s Office for the District of Massachusetts, the Defendants have only speculated, but have not adequately demonstrated, that the requested information is exculpatory or material. The fact that the investigations at issue involved Risperdal or other specified products helps to explain why the Defendants might wish to obtain the information but it does not necessarily make the information *per se* exculpatory or material. Moreover, the Court does not deem information held by other U.S. Attorney’s Offices to be within the custody, possession or control of the government for purposes of the present matter. *See e.g., U.S. v. Prange*, 11-cr-10415-NMG, 2012 WL 3263606, *1 (D. Mass. Aug. 7, 2012) (other United States Attorney’s Offices not part of “prosecution team” for purposes of discovery where their only involvement in the case was to facilitate arrests of out of district defendants).

With respect to the present matter, the Government did provide the Defendants via letter with several excerpts from two letters written by counsel for J&J, dated June 24 and December

20, 2013. The selected excerpts purportedly describe certain statements or expected statements of potential witnesses. The Government subsequently submitted unredacted copies of the letters to the Court for an *in camera* review. Having reviewed the letters, the Court is satisfied that the Government has produced those portions of the letters that could be viewed as exculpatory or material, with one exception. The government produced among other things the first paragraph on page 20 of the December 20, 2013 letter, but redacted the first two sentences of the paragraph. It is not clear why the government redacted those sentences and in the Court's view including them would help, even if only marginally, to provide better context for the information that follows. Accordingly, the Government is ordered to produce the complete first paragraph of page 20 of the December 20, 2013 letter.

B. Redacted Memoranda of Interviews

The Defendants seek complete copies of ten memoranda of interviews which the Government previously produced in redacted form. At oral argument, the Government was ordered to submit unredacted copies of the memoranda to the Court for an *in camera* review. Following that review, the Court orders that the Government produce the memoranda of the July 31, 2014 12:10 p.m. interview (Exhibit M to the Government's *in camera* submission) without redaction. In this context, where the Government has taken the position that it will produce memoranda of interview in their entirety unless there is a principled reason to withhold some portion, the Court does not believe that redaction of Exhibit M was proper. The Court finds that redaction of the remaining memoranda (Exhibits D through L to the Government's *in camera* submission) was proper.

C. Subpoenas

The Defendants seek copies of the government's subpoenas to 3rd parties. The Defendants argue that Court should order production of the subpoena under its inherent authority to control litigation because the subpoenas will allow the Defendants to better understand the universe of documents the subpoenaed entities produced in response to the subpoenas, and more quickly determine whether further document requests to particular witnesses might be warranted.

While the Court appreciates the large volume of documents at issue in this case, it has not been persuaded that requiring the government to produce the subpoenas will substantially aid the Defendants in the way they might hope. First, the Government has represented that the document categories in the subpoenas are too general to help the Defendants narrow their document review. Second, the categories of documents that were produced by an entity may not cleanly mirror the categories of documents asked for by the subpoenas themselves. For example, and as the government argued, it is common for a party responding to a subpoena to negotiate to limit the scope of their production or to object to producing certain documents, such that what is ultimately produced may differ in scope and type from what was initially sought. For that reason, the government argues, the subpoenas would be of limited value and would do little more than to provide the Defendants with greater insight into the Government's investigation.

Accordingly, this portion of the Defendants' motion to compel is denied.

D. Agent Notes Regarding Witness Interviews

The Defendants have moved to compel the production of agent notes taken during various witness interviews, but clarified at the hearing that they seek the notes only to the extent that they are exculpatory or inconsistent with the 302 reports. This request is consistent with case law. See, e.g., *United States v. Serrano*, No. 07-cr-0118, 2008 WL 1846577, *1 (C.D. Cal.

Apr. 21, 2008) (holding that interview notes should be produced if they are exculpatory or conflict with Form 302 report such that they can be used for impeachment). The Government has acknowledged its obligations and represented that it is currently in the process of reviewing the notes for inconsistencies and potentially exculpatory information. Based upon the Government's representation, the Court denies as moot this portion of the Defendants' motion to compel.

E. Stratus Devices

The Defendants seek production of at least forty Stratus devices from unexpired lots. The Government states that it does not know how many Stratus devices currently exist. The parties agreed at the hearing to work together to equitably divide whatever number of devices remain, rendering this request moot.

F. Citizen Petitions to FDA Regarding Intended Use

The Defendants seek documents related to the FDA's consideration of two specific citizen's positions dealing with the meaning of the phrase "intended use." The Defendants contend that these documents are both relevant to the meaning of "intended use," and potentially exculpatory to the extent they may show that the meaning of "intended use" has been a subject of confusion by manufacturers for many years, which in turn, the Defendants argue, would prevent a finding that they willfully violated the law. The Government argues that the non-public understanding of government employees regarding the meaning of regulations is not relevant to either the construction or potential vagueness of the statutes and regulations at issue.

The Court agrees that the FDA's non-public internal statements regarding the meaning of "intended use" have no bearing on how that term should be construed in this case. *United States v. Lachman*, 387 F.3d 42, 54-55 (1st Cir. 2004). Whether such statements are relevant to the

issue of the willfulness of the Defendants' alleged violations is a more difficult question. Due process requires that a defendant be given fair notice that his conduct is prohibited before liability may be imposed. *Gen. Elec. Co. v. U.S. Environmental Protection Agency*, 53 F.3d 1324, 1328 (D.C. Cir. 1995). Where the agency responsible for administration and enforcement of a particular regulation "issues contradictory or misleading public interpretations of a regulation, there may be sufficient confusion for a regulated party to justifiably claim a deprivation of fair notice." *Lachman*, 387 F.3d at 57; see also *United States v. Ward*, No. 00-681, 2001 WL 1160168, at *16 (E.D. Pa. Sept. 5, 2001) ("A defendant should not be penalized for violating a regulation the interpretation of which cannot be agreed upon by those who are responsible for its administration and enforcement."). Although non-public statements by agency employees arguably also tend to show that a regulation is ambiguous, the First Circuit, in its 2004 *Lachman* decision, seemed to foreclose criminal defendants' use of non-public agency statements to support a vagueness argument. There, the Court specifically rejected the argument that the line of vagueness cases discussing conflicting public agency interpretations of regulations should be read to include situations involving conflicting *internal* agency statements. *Lachman*, 387 F.3d at 58 ("Nothing in the *General Electric / Trinity Broadcasting* line of cases suggests that such non-public statements may create the kind of confusion that supports a finding of a due process violation.").

However, the First Circuit in its 2008 *Lachman* decision arguably leaves open the possibility that non-public agency statements might be used to support a good faith defense in cases where there is some evidence that the defendant acted in the good faith belief that his conduct was lawful, and that the agency's internal analysis bolsters the reasonableness of the defendant's interpretation of the law. *United States v. Lachman*, 521 F.3d 12, 19 (1st Cir. 2008).

Here, though, the Defendants have stated that they intend to raise a good faith defense, but they have not adequately articulated specifically how the FDA's internal discussions regarding the meaning of "intended use" are relevant to their defense in light of the intent element of the offenses charged. The Court is reluctant to allow the broad discovery sought against this backdrop, especially where there is apparently no issue that everyone will be entitled to learn the FDA's final conclusions once it has completed its review. This portion of the motion to compel is therefore denied.

G. Promises, Rewards and Inducements

The Defendants seek disclosure of all promises, rewards or inducements communicated orally to any witness. The Government subsequently represented in open court that it has not made any oral promises, rewards or inducements to any witness in this case, rendering this request moot.

II. CONCLUSION

For the foregoing reasons, the Court GRANTS the Defendants' motion with respect to Request Nos. 8 and 11 as described above. The Defendants' motion is otherwise DENIED.

/s/ Donald L. Cabell
DONALD L. CABELL, U.S.M.J.

DATED: October 28, 2015